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NOV 16 2005

510(K) Summary

Date: August 31, 2005

Submitted by: Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4382
Fax: 386-462-3821

Proprietary Name:
STERLING® Interference Screw HT

Common Name:
Screw, fixation, bone

Classification:
HWC, orthopedics panel

Code Section:
21 CFR 888.3040

Substantial Equivalence:
The STERLING® Interference Screw HT is equivalent to the STERLING® Interference Screw ST in materials, design, and function.

Description:
The STERLING® Interference Screw HT is machined from processed bovine cortical bone, with lengths ranging from 20 to 35mm and diameters ranging from 7 to 12 mm. The STERLING® Interference Screw HT is threaded and has an external squared-drive.

Intended Use:
The STERLING® Interference Screw HT is intended for use in an arthroscopic or open ACL and/or PCL reconstruction by a trained medical professional.

Summary of Technological Characteristics:
The STERLING® Interference Screw HT and the STERLING® Interference Screw ST have equivalent materials, design and function. The STERLING® Interference Screw HT is constructed of bovine bone and is equivalent in materials to another 510(k)-cleared product, the STERLING® Interference Screw ST. The source of bovine bone used in the manufacture of STERLING® Interference Screw HT is a closed herd located in the U.S.A.

The STERLING® Interference Screw HT has been shown to remodel comparably to allograft in an animal model. A viral inactivation study using a worst-case representation of the BioCleanse® process, used in the manufacture of STERLING® Interference Screw HT, has shown greater than a six log reduction of a panel of viruses to below detectable limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Ms. Carrie Hartill
Regeneration Technologies, Inc.
11621 Research Circle
P.O. Box 2650
Alachua, Florida 32615

Re: K052405
Trade/Device Name: Sterling® Interference Screw HT
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 31, 2005
Received: September 13, 2005

Dear Ms. Hartill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052405

Device Name: STERLING® Interference Screw HT

Indications for Use: The STERLING® Interference Screw HT is used to provide interference fixation in anterior cruciate ligament reconstruction using a bone-tendon-bone graft; fixation during posterior cruciate ligament reconstruction utilizing a bone-tendon-bone graft.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

K052405

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052405